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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,079	YAMAMOTO, JANET K.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43 and 50-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35,37 and 50-63* is/are rejected.

7)☒ Claim(s) *36 and 38-43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's third after-final amendment filed August 8, 2005 is acknowledged and entered. Claims 31-43 and 50-63 are pending and under examination. Upon further consideration of the claimed subject matter, prosecution on the merits is re-opened and the finality of the office action on February 8, 2005 is withdrawn. Any inconvenience to Applicant is regretted.

Claim Rejections - 35 USC § 112

2. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the FIV strains *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in claim 37. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet*. See 37 CFR 1.802. One cannot practice the claimed invention without these strains. Therefore, access to *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* is required to practice the invention. The specification does not provide a repeatable method for obtaining *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* without access to the *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* and they do not appear to be readily available material.

Deposit of *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-35, 50, 51, 53-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto *et al.* (US 5,275,813, " '813 Patent ") in view of Sodora *et al.* (*Journal of Virology*, 1994, 68(4):2230-2238, " Sodora ") and Zagury *et al.* (WO 92/00098, " Zagury "). The claims are drawn to a vaccine composition that induces an immune response against two or more subtypes of FIV in an animal susceptible to infection by FIV, comprising an effective amount of an FIV immunogen to induce said immune response, wherein the immunogen comprises an immunogen or immunogens from or comprising at least two different FIV subtypes. The immunogen can be synthetic peptides, natural or recombinant proteins or immunogenic fragments, cell-free whole or partial FIV virus, or a cell infected with FIV. The virus or FIV-infected cell is inactivated or attenuated prior to administration, respectively. The FIV subtypes include A, B, C and D. Specifically, the animal is a cat, and the immunogen is an envelope glycoprotein or immunogenic fragment thereof. The protein can be a chimeric protein comprising amino acid sequences from at least two different FIV subtypes. The vaccine further comprises an adjuvant and is administered in a variety of routes and doses.

The '813 Patent teaches vaccination of cats with FIV, including inactivated whole virus, attenuated virus, inactivated cell lines infected with virus, antigens and subunit vaccines comprising proteins and polypeptides thereof (abstract and col. 2, lines 19-35). The administration of the FIV immunogens results in an immune response. Methods of administration include subcutaneous, intramuscular and oranasal (col. 2, lines 36-44) with an adjuvant such as incomplete Freund's (col. 9, lines 51-61). Polypeptides include haptenic and antigenic portions of FIV, such as epitopes (col. 8, lines 14-28). The '813 Patent teaches that

different strains of FIV, not yet discovered, would also be useful for producing more immunogens and inducing cross-reactivity among other strains (col. 6, line 22 through col. 7, lines 1-8.) Also taught are chimeric proteins incorporating FIV immunogens (col. 11, lines 45-61). Dosages range from 0.1 mg to about 5 mg, or more specifically, 0.2 mg to 2 mg. The amount of virus in the dose is from about 10^6 to 10^8 cells, usually about $5x10^6$ to $5x10^7$ cells (col. 12, lines 12-25). The '813 Patent does not specifically teach a dual-subtype or multi-subtype vaccine, env protein, or subtypes A, B, C and/or D.

However, Sodora teaches multiple subtypes of FIV including A, B, C, D, E, F and O (page 2230, col. 1, first full paragraph). Sodora discloses a comparison of FIV env from different isolates to determine variability and relatedness among different subtypes.

It would have been obvious to use multiple subtypes of FIV for vaccination in the method of the '813 Patent. One of ordinary skill in the art would be motivated to use multiple subtypes, as taught by Sodora, in order to maximize the immune response against as many strains as possible. Also, the '813 Patent teaches that different strains of FIV, not yet discovered, would also be useful for producing more immunogens and determining cross-reactivity (col. 6, line 22 through col. 7, lines 1-8.) Zagury teaches a multiple strain composition for HIV (Zagury, abstract), for which FIV is a model of infection ('813 Patent abstract, and Sodora, page 2230, columns 1 and 2, bridging paragraph). Zagury teaches that peptide sequences from several strains will induce a broad immune response (page 4, lines 21-24). One would have had a reasonable expectation of success that an FIV multi-subtype vaccine would have worked because cocktail vaccines are known to be effective for inducing an immune response against multiple pathogens, evidenced by Zagury's multiple subtype immunodeficiency composition.

With regard to the choice of envelope protein, the '813 Patent does not specifically disclose the use of envelope. However, the Patent does teach the use of polypeptides that include haptenic and antigenic portions of FIV, such as epitopes (col. 8, lines 14-28). One of ordinary skill the art would readily recognize the envelope protein (characterized by Sodora) as comprising antigenic determinants.

With regard to the embodiment of a chimeric protein comprising amino acid sequences of a protein from at least two different FIV subtypes, one of ordinary skill would have been motivated to design FIV chimeric proteins by the '813 Patent's disclosure that chimeric proteins incorporating FIV immunogens are contemplated (col. 11, lines 45-61). A chimeric protein having antigens from more than one subtype would induce a broader immune response.

Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

4. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over the '813 Patent in view of Sodoro and Zagary as applied to claims 31-35, 50 and 51 above, and further in view of Yamamoto *et al.* (*Journal of Virology*, 1993, 67(1):601-605, " Yamamoto ").

The combined teachings of the '813 Patent in view of Sodoro and Zagary are summarized above. The combination does not teach SEQ ID NO: 1. However, Yamamoto discloses SEQ ID NO: 1, an FIV envelope peptide for diagnostic purposes. One would have been motivated to use Yamamoto's envelope peptide in the vaccine of the '813 Patent because the '813 Patent suggests the use of FIV proteins, among other immunogens ('813 abstract). One would have had a reasonable expectation of success that the peptide of Yamamoto would have induced an immune

response because envelope protein is an antigenic determinant that is bound by antibodies, evidenced by Yamamoto's use of the peptide in a diagnostic assay. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37, 42 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 5,846,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients of the instant claims and the patented claims are drawn to deposited FIV-infected cell lines of at least FIV strains *Dix*, *UK8*, *Bang, Aom1*, *Aom2, Shi*, and *Pet*. Because claims 2 and 4 include at least one of these strains (thus encompassing more than one strain) the patented claims are encompassed by instant claims 37, 42 and 43.

Conclusion

6. Claims 36-43 are free of the prior art of record. Claim 36 is drawn to a non-obvious embodiment of a combination of FIV subtypes A and D. Claim 37 is drawn to a non-obvious embodiment of a combination of FIV strains that were discovered by Applicant. Claims 38-43 are drawn to combinations of novel deposited cell lines. Claims 38-43 are objected to for depending from rejected claims.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
Stacy B. Chen
September 13, 2005

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